510(k) Summary for
Dimension Vista® System Bilirubin Calibrator
(BILI CAL – KC210)

510 (k) Number: K072717

DEC 1 2 2007

Analyte: Bilirubin

Type of Test: Calibrator Material

Applicant:

Dade Behring Inc .
P.O. Box 6101
Newark, DE 19714-6101
Helen M. Lee Regulatory Affairs and Compliance Manager
Office Phone: 302.631.8706
Fax: 302.631.6299

Proprietary and Established Name:
Dimension Vista® System Bilirubin Calibrator (BILI CAL – KC210)

Regulatory Information:

Regulation Section: 21 CFR § 862.1150 - Calibrator

Classification: Class II

Product Code: JIT – Calibrator, Secondary

Panel: Clinical Chemistry

Intended Use: The BILI CAL is an *in vitro* diagnostic product for the calibration of Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods on the Dimension Vista® System.

Device Description: The BILI calibrator is a two level calibrator. Level 1, purified system water, is provided on-board the Dimension Vista® System. Level 2 is a liquid, bovine serum albumin based material spiked with ditaurobilirubin and traceable to NIST Standard Reference Material 916a.

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(BILI CAL – KC210)

Substantial Equivalence Information:

Predicate Device: Dimension Vista™ System TBIL Flex reagent cartridge and TDBIL Calibrator (k061719).

Comparison to the Predicate Device:

Attribute	Dimension Vista™ System TDBIL Calibrator (Predicate)	Dimension Vista® System BILI Calibrator (Proposed)
Intended Use	The TDBIL CAL is an *in vitro* diagnostic product for calibration of the Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods on the Dimension Vista™ System.	The BILI CAL is an *in vitro* diagnostic product for calibration of the Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods on the Dimension Vista® System.
Analyte	Ditaurobilirubin	Ditaurobilirubin
Matrix	Human Serum	Bovine Serum
Levels Bilirubin Concentration in (mg/dL) Total (TBIL) Direct (DBIL)	One (CAL A) Level 1- is on-board, purified system water Level 2 (27.5) Level 2 (19.25)	One (CAL A) Level 1- is on-board, purified system water Level 2 (27.5) Level 2 (17.5)
Form	Lyophilized	Liquid
Volume	3 vials, 1 mL each vial (hydrated volume)	3 vials, 2.5 mL each
Traceability	National Institute of Standards and Technology (NIST), Standard Reference Material (SRM) 916a.	National Institute of Standards and Technology (NIST), Standard Reference Material (SRM) 916a.

Comments on Substantial Equivalence:

Both the proposed Dade Behring Dimension Vista® BILI Calibrator and the existing Dimension Vista® TDBIL Calibrator are in vitro diagnostic products for calibrating the DBIL and TBIL methods.

Conclusion:

The Dimension Vista® BILI Calibrator is substantially equivalent to the Dimension Vista™ TDBIL Calibrator based upon the comparison discussed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 2 2007

Dade Behring Inc.
c/o Ms. Helen M. Lee,
Regulatory Affairs & Compliance Manager
P.O. Box 6101, Mail Box 514
Newark, DE 19714-6101

Re: k072717
Trade Name: Dimension Vista® System Bilirubin Calibrator (BILI CAL – KC210)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: November 05, 2007
Received: November 06, 2007

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 809); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072717

Device Name:

Dimension Vista® System BILI Calibrator (KC210)

Indications for Use:

The BILI CAL is an *in vitro* diagnostic product for the calibration of the Direct Bilirubin (DBIL) and Total Bilirubin (TBIL) methods on the Dimension Vista® System.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use_____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K072717